

FEB 5 2007

510 K SUMMARY

Date: January 04, 2007  
Aspect Medical Systems, Inc.,  
One Upland Road, Norwood MA 02062

Contact Person: Vikram Verma  
Phone: (617) 559-7134  
Fax: (617) 559-7948

Proprietary Name: Zipprep Electrode  
Common Name: Electrode, Cutaneous Electrode  
Classification: Class II device. Refer to 21 CFR 882.1320  
Product Code: GXY

Predicate Devices: Aspect Medical Systems Zipprep Electrode  
510(k), # K940802, received FDA clearance on June 22, 1994.  
  
Aspect Medical Systems Zipprep EEG Sensor  
510(k)#K961821, received FDA clearance on October 04, 1996.

Device Description: The Zipprep Electrode is a single patient use, disposable pre-gelled electrode that is applied directly to the patient's forehead to record electro-physiological signals.

Indications for Use: The Zipprep Electrode is applied directly to the patient's skin to enable recording of physiological signals.

Similarities and Differences:

Similarities:

- Same indications for use.
- Same intended use.
- Same fundamental scientific technology.
- Incorporates the same basic design.
- Biocompatible.

Differences:

The Zipprep Electrode has the following minor differences from the predicate device:

- Shape changed from “tear drop” to “rectangular”.
- Stainless steel snap stud
- Polypropylene tape
- 18 month shelf life

Biocompatibility testing, in accordance with ISO10993, and electrical testing as per ANSI-AAMI EC12:2000 have been referenced to support the device.

In summary, the Zipprep Electrode is substantially equivalent to the predicate device. Aspect Medical Systems believes these modifications do not raise new questions of safety or effectiveness. The intended use is the same as the predicate device. The indications for use remain the same as the Zipprep Electrode and Sensor. The fundamental scientific technology remains the same as the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Aspect Medical Systems, Inc.  
% Mr. Vikram Verma  
Manager, Regulatory Affairs  
and Quality Assurance  
1 Upland Road  
Norwood, Massachusetts 02062

FEB 5 2007

Re: K070069  
Trade/Device Name: Zipprep Electrode  
Regulation Number: 21 CFR 882.1320  
Regulation Name: Cutaneous electrode  
Regulatory Class: Class II  
Product Code: GXY  
Dated: January 5, 2007  
Received: January 8, 2007

Dear Mr. Verma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

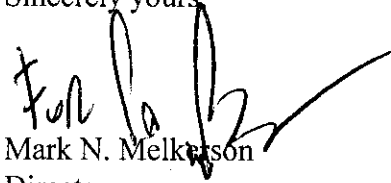
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson

Director

Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Indications for Use Statement

510(k)  
Number  
(if known)

K070069

Device Name      Zipprep Electrode

Indications

For Use

The Zipprep Electrode is applied directly to the patient's skin to enable recording of physiological signals.

Prescription Use ☒ X  
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use  
(21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF  
NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

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510(k) Number

K070069

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